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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,580	05/22/2000	Frank McKeon	HMSU-P01-048	1156
25181	7590 04/18/2005		EXAMINER	
FOLEY HO	•	KAM, CHIH MIN		
PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			ART UNIT	PAPER NUMBER
			1653	
			DATE MAILED: 04/18/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
Office Action Summers	09/575,580	MCKEON ET AL.			
Office Action Summary	Examiner	Art Unit			
	Chih-Min Kam	1653			
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the	correspondence address			
A SHORTENED STATUTORY PERIOD FOR REPL' THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a repl - If NO period for reply is specified above, the maximum statutory period or - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be y within the statutory minimum of thirty (30) d will apply and will expire SIX (6) MONTHS fro c, cause the application to become ABANDON	timely filed  ays will be considered timely.  rm the mailing date of this communication.  NED (35 U.S.C. § 133).			
Status					
1)⊠ Responsive to communication(s) filed on <u>16 M</u>	larch 2005.				
	s action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)⊠ Claim(s) <u>8-13</u> is/are pending in the application					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5)⊠ Claim(s) <u>8-10 and 12-13</u> is/are allowed.					
6) Claim(s) 1/ is/are rejected.	•				
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.					
	,				
Application Papers		·			
9) The specification is objected to by the Examine					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12)☐ Acknowledgment is made of a claim for foreign a)☐ All b)☐ Some * c)☐ None of:	priority under 35 U.S.C. § 119(	a)-(d) or (f).			
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau	ו (PCT Rule 17.2(a)).				
* See the attached detailed Office action for a list	of the certified copies not receive	ved.			
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summar	ry (PTO-413)			
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail [	Date			
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	5)  Notice of Informal 6)  Other:	Patent Application (PTO-152)			
J.S. Patent and Trademark Office PTOL-326 (Rev. 1-04) Office Ac	etion Summary F	Part of Paper No./Mail Date 20050406			

#### **DETAILED ACTION**

1 The finality of previous Office Action dated October 13, 2004 is withdrawn due to a new ground of rejection.

### Status of the Claims

2. Claims 8-13 are pending.

Applicants' amendment filed March 16, 2005 is acknowledged. Applicants' response has been fully considered. Claims 1-3, 5-7 and 14-16 have been cancelled. Therefore, claims 8-13 are examined.

#### **Objection Withdrawn**

3. The previous objection to the specification regarding new matter and "ATCC Deposit No." is withdrawn in view of applicants' amendment to the specification, applicant's cancellation of claim 2, and applicants' response at page 3 in the amendment filed March 16, 2005.

#### Rejection Withdrawn

#### Claim Rejections - 35 USC § 112

4. The previous rejection of claim 2 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' cancellation to the claim, and applicants' response at page 3 in the amendment filed March 16, 2005.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 11 is directed to the use of antibodies of 9A11, 25 D6, 11E1, 16G5 and 3F4A, which have been generally against Csp2 (page 134, lines 12-20), in the method of identifying a compound that modulates the activity or level of a calcipressin (Csp) protein. It is apparent that 9A11, 25 D6, 11E1, 16G5 and 3F4A antibodies are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Applicant is reminded that the following and should amend the specification accordingly.

The current address of the ATCC is as follows:

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209.

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If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

NOTE THE CURRENT ATCC DEPOSITORY ADDRESS

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite because 9A11, 25 D6, 11E1, 16G5 and 3F4A are designated names for the antibodies in the laboratory, it is not clear what these antibodies are.

#### Conclusion

7. Claim 11 is rejected, and it appears that claims 8-10 and 12-13 are free of art and allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.

Patent Examiner

**CMK** 

April 6, 2005

JON WEBER SORY PATENT EXAMINER